

REMARKS

Claims 1-14, 16-18 and 20-59 will be pending upon entry of this Amendment D. Claim 1 has been amended to further comprise an antioxidant selected from the group consisting of butylated hydroxyanisole (BHA), butylated hydroxytoluene (BHT), carotenoids, filtered wheat germ oil, gamma oryzanol, sodium sulfite, grape seed extract, green tea extract, rosmarinic acid, ubiquinone, lipoic acid, N-acetyl-cysteine, avocado, sage, proanthocyanidins, and mixtures thereof. Support for this amendment can be found in originally filed dependent claim 19. Claims 31-59 have been withdrawn as directed to a non-elected invention. Applicants reserve the right to file divisional applications directed to the non-elected claims.

Applicants respectfully request reconsideration and allowance of all pending claims.

1. Rejection of the Claims under 35 U.S.C. §103(a)

Reconsideration is requested of the rejection of claims 1-30 under 35 U.S.C. §103(a) as being unpatentable over Klofta, et al. (U.S. Patent No. 6,238,682) in view of Krzysik, et al. (U.S. Patent No. 6,440,437).

Claim 1, as amended herein, is directed to a tissue product comprising a tissue paper and a moisturizing and lubricating composition. The moisturizing and lubricating composition comprises from about 1% (by weight) to about 40% (by weight) of an emollient, from about 1% (by weight) to about 20% (by weight) of a humectant, from about 30% (by weight) to about 90% (by

weight) an immobilizing agent, from about 0.1% (by weight) to about 30% (by weight) of a skin barrier enhancing agent, from about 1% (by weight) to about 40% (by weight) of a compatibilizing agent, and an antioxidant selected from the group consisting of butylated hydroxyanisole (BHA), butylated hydroxytoluene (BHT), carotenoids, filtered wheat germ oil, gamma oryzanol, sodium sulfite, grape seed extract, green tea extract, rosmarinic acid, ubiquinone, lipoic acid, N-acetyl-cysteine, avocado, sage, proanthocyanidins, and mixtures thereof, wherein no more than about 50% (by weight) of the components are liquid at room temperature and no less than about 50% (by weight) of the components are solid at room temperature, and wherein at least about 85% (by weight) of the components of the moisturizing and lubricating composition form a single phase at a temperature of from about 45°C to about 80°C.

Klofta, et al. disclose an anhydrous lotion composition for killing viruses and bacteria in addition to imparting a soft, lubricious, lotion-like feel when applied to tissue paper. The lotion composition comprises at least one antimicrobial selected from an antiviral, antibacterial, and mixtures thereof; at least one hydrophilic solvent; at least one skin conditioning agent; and at least one hydrophilic surfactant. When used in the lotion formulation, the antiviral is present in the lotion composition in an amount of from about 1% (by weight) to about 60% (by weight) and the antibacterial is present in an amount of from about 0.1% (by weight) to about 6% (by weight). Hydrophilic solvents can include glycol type solvents such as polyethylene glycols, glycerin, ethylene glycol, propylene

glycol, polypropylene glycol, ethanol, isopropanol, hexylene glycol, and mixtures thereof and are present in the lotion composition in an amount of from about 5% (by weight) to about 60% (by weight).¹ Hydrophilic surfactants such as ethoxylated alcohols are present in the lotion formulation in an amount of from about 0.1% (by weight) to about 60% (by weight). Skin conditioning agents include petroleum-based agents such as mineral oil and petrolatum; fatty acid ester type agents, fatty alcohol type agents, dimethicones including functionalized derivatives of dimethicones, polyethylene glycols, or mixtures thereof and are present in the lotion composition in an amount of from about 0.1% (by weight) to about 60% (by weight).² Typically, the skin conditioning agents have either a plastic or fluid consistency at 20°C (i.e., ambient temperatures).³ As the skin conditioning agents have a plastic or fluid consistency at 20°C, they tend to flow or migrate on the surface of the tissue product. The lotion composition can further optionally include an immobilizing agent such as C₁₂-C₂₂ fatty alcohols and C₁₂-C₂₂ fatty acids in amounts of from about 5% (by weight lotion formulation) to about 60% (by weight lotion formulation).⁴

Significantly, Klofta, et al. fail to disclose that their lotion formulation includes from about 0.1% (by weight) to about 30% (by weight) of a skin barrier enhancing agent as required in claim 1. Further, Klofta, et al. fail to disclose that their lotion formulation includes an antioxidant selected from the

¹ U.S. 6,238,682 at column 17, lines 41-42.

² *Id.* at column 19, lines 23-26.

³ *Id.* at column 17, lines 50-52.

⁴ *Id.* at column 22, lines 51-55.

group consisting of butylated hydroxyanisole (BHA), butylated hydroxytoluene (BHT), carotenoids, filtered wheat germ oil, gamma oryzanol, sodium sulfite, grape seed extract, green tea extract, rosmarinic acid, ubiquinone, lipoic acid, N-acetyl-cysteine, avocado, sage, proanthocyanidins, and mixtures thereof as required in claim 1.

Recognizing that Klofta, et al. fail to make such a disclosure, the Office cites Krzysik, et al. for combination with the Klofta, et al. reference. Specifically, the Office states that it would have been obvious to a person having ordinary skill in the art to combine the cited references as there would be an improved beneficial effect of a soft and lubricious feel and a better maintained skin barrier function.

Krzysik, et al. disclose a skin health enhancing soft wet wipe comprising an oil-in-water emulsion composition. The oil-in-water composition comprises a natural fat or oil, sterol or sterol derivative, humectant, emulsifying surfactant, and water. Specifically, in one exemplary embodiment, the oil-in-water composition comprises from about 0.1 to about 30 weight percent of natural fats or oils, from about 0.1 to about 10 weight percent of a sterol or sterol derivative, from about 0.1 to about 99.5 weight percent of an humectant, and from about 0.5 to about 20 weight percent of an emulsifying surfactant having an HLB range of about 7 to about 18, from about 45 to about 99.5 weight percent of water and the pH of the emulsion adjusted to a pH of about 4 to about 7.⁵

⁵ U.S. 6,440,437 at column 3, lines 21-29.

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Significantly, no where in Krzysik, et al. is it taught or suggested that the oil-in-water composition contains an antioxidant selected from the group consisting of butylated hydroxyanisole (BHA), butylated hydroxytoluene (BHT), carotenoids, filtered wheat germ oil, gamma oryzanol, sodium sulfite, grape seed extract, green tea extract, rosmarinic acid, ubiquinone, lipoic acid, N-acetyl-cysteine, avocado, sage, proanthrocyanidins, and mixtures thereof.

In order for the Office to show a *prima facie* case of obviousness, M.P.E.P. §2143 requires that the Office must meet three criteria: (1) the prior art references must teach or suggest all of the claim limitations; (2) there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to combine and/or modify the references, and (3) there must be some reasonable expectation of success. An obviousness determination is not the result of a rigid formula disassociated from the consideration of the facts of the case. The common sense of those skilled in the art can demonstrate why some modifications and/or combinations would have been obvious where others would not.⁶ As noted in the Examination Guidelines For Determining Obviousness Under 35 U.S.C. §103(a) in view of the Supreme Court decision in KSR Int'l Co. v. Teleflex, Inc., et al.⁷, the Office must provide an explanation to support any obviousness rejection. The Office has clearly failed to meet

⁶ Leapfrog Enterprises, Inc. v. Fisher-Price, Inc., No. 06-1402 (Fed. Cir. May 9, 2007) See also KSR Int'l Co. v. Teleflex, Inc., et al. 550 US_____, 2007 WL 1237837 at 12 (2007).

⁷ 550 US_____, 2007 WL 1237837 at 12 (2007)

its burden under numbers (1) and/or (2) above, as the cited references do not teach or suggest all of the claimed limitations and there is no apparent reason to combine and/or modify the references to arrive at each and every limitation of Applicants' claim 1. It simply would not have been obvious to one skilled in the art to arrive at Applicants' claimed combinations.

Initially, as noted above, neither the Klofta, et al. reference nor the Krzysik, et al. reference, considered alone or in combination, teach or suggest including an antioxidant in their lotion, wherein the antioxidant is selected from the group consisting of butylated hydroxyanisole (BHA), butylated hydroxytoluene (BHT), carotenoids, filtered wheat germ oil, gamma oryzanol, sodium sulfite, grape seed extract, green tea extract, rosmaric acid, ubiquinone, lipoic acid, N-acetyl-cysteine, avocado, sage, proanthrocyanidins, and mixtures thereof. Specifically, in addition to the emollient, humectant, immobilizing agent, compatibilizing agent, and skin barrier enhancing agent, the composition of claim 1 includes an antioxidant selected from the group consisting of butylated hydroxyanisole (BHA), butylated hydroxytoluene (BHT), carotenoids, filtered wheat germ oil, gamma oryzanol, sodium sulfite, grape seed extract, green tea extract, rosmaric acid, ubiquinone, lipoic acid, N-acetyl-cysteine, avocado, sage, proanthrocyanidins, and mixtures thereof to minimize or eliminate the development of an offensive odor. As such, this is a significant aspect of Applicants' invention. As the cited references fail to make such a disclosure, the cited references

fail to teach or suggest each and every limitation of Applicants' claim 1 as required under MPEP §2143.

Furthermore, even if the cited references did show each element of Applicants' claim 1 (which they do not as Applicants' have explained above), the common sense of one ordinarily skilled in the art would not have provided a reason to combine the Klofta, et al. reference and the Krzysik, et al. reference to arrive at Applicant's composition of claim 1.

As noted in M.P.E.P. §2142, in establishing obviousness, the Office must show references that teach all of the claimed limitations along with some reason, either in the references themselves or in knowledge generally available to one skilled in the art, to modify and/or combine the references and arrive at the claimed subject matter. The mere fact that the references can be modified and combined to arrive at the claimed subject matter does not render the resultant combination obvious, unless the prior art also suggests a reason for the combination. *In re Mill*, 916 F.2d 680, 16 USPQ2d 1430 (Fed. Cir. 1990). While this test is not a rigid formula, it does provide helpful insight as it can be important to identify a reason that would have prompted a person of ordinary skill in the art to modify the elements as the new invention does. A close reading of the cited references clearly indicates that one skilled in the art would not have been so motivated and, without Applicants' disclosure as a blueprint (which the Office had the benefit of utilizing), such a combination of the formulations of the

Klofta, et al. and the Krzysik, et al. references would not have been made.⁸

Applicants assert that there is nothing in the cited references or in the general knowledge of one ordinarily skilled in the art, to combine the Klofta, et al. and Krzysik, et al. references to arrive at Applicants' amended claim 1. Specifically, a close reading of the Krzysik, et al. reference actually teaches away from the combination of the Klofta, et al. and Krzysik, et al. references. Specifically, as recognized by the Supreme Court in KSR International Co. v. Teleflex, Inc., while an obviousness determination is not a rigid formula, the TSM (teaching, suggestion, motivation) test captures a helpful insight: "A patent composed of several elements is not proved obvious merely by demonstrating that each element was, independently, known in the art. Although common sense directs caution as to a patent application claiming as innovation the combination of two known [elements] according to their established functions, it can be important to identify a reason

⁸ M.P.E.P. §2142 further provides that in order to reach a proper determination under 35 U.S.C. §103(a), the Examiner must step backward in time and into the shoes worn by the hypothetical "person of ordinary skill in the art" when the invention was unknown and just before it was made. Knowledge of Applicants' disclosure must be put aside in reaching this determination, yet kept in mind in order to determine the "differences." The tendency to resort to "hindsight" based upon Applicants' disclosure is often difficult to avoid due to the very nature of the examination process. However, as stated by the Federal Circuit, impermissible hindsight must be avoided and the legal conclusion must be reached on the basis of the facts gleaned from the prior art. *Grain Processing Corp. v. American-Maize-Products, Co.*, 840 F.2d 902, 904 (Fed. Cir. 1988).

that would have prompted a person of ordinary skill in the art to combine the elements as the new invention does."⁹ More particularly, a court must ask whether the improvement is more than the predictable use of prior-art elements according to their established functions.¹⁰ If a person of ordinary skill in the art can implement a predictable variation, and would see the benefit of doing so, §103 likely bars its patentability.

Specifically, as disclosed in Klofta, et al., it is desirable for the lotion compositions to be **anhydrous** lotions, typically comprising less than about 5% (by weight) water, preferably about 1.0% (by weight) or less water, more preferably about 0.5% (by weight) or less water, and most preferably about 0.1% (by weight) or less water.¹¹ Moreover, Klofta, et al. explain that the "anhydrous nature of these lotions allows for more efficient dry transfer of the lotion to the skin. Intentional addition of water to the lotion would be detrimental to physical properties of the paper such as tensile and caliper. Water aids in the migration of the lotion throughout the web. This leads to fiber debonding and less lotion concentrated at the surface of the paper. This leads to both tensile and caliper losses; thus, it is beneficial to maintain an anhydrous lotion state as described herein."¹² As noted above, however, the Krzysik, et al. composition comprises from about 45% to about 99.5% by weight water. The water contained in the Krzysik, et al. composition may be a mixture of water and

⁹ *Id.* at 5.

¹⁰ *Id.*

¹¹ U.S. 6,238,682 at column 10, lines 51-57.

¹² *Id.* at column 10, lines 57-65.

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alcohol. The amount of alcohol in the water is up to about 70 weight percent of the water and alcohol solution.¹³ Even if alcohol is present in 70 weight percent of the water and alcohol solution, however, the compositions of Krzysik, et al. comprise at least about 13.5% by weight water. As such, there is no apparent reason why one skilled in the art would combine the components of the Krzysik, et al. reference, which are desirably incorporated into compositions having at least 13.5% by weight water with the lotion compositions of Klofta, et al., which desirably comprise less than 5% (by weight) water. As such, there is no apparent reason to combine the cited references to arrive at each and every limitation of Applicants' claim 1. As such, claim 1 is patentable over the cited references.

The Examiner submits on page 10, paragraph 5, that the compositions of the Klofta, et al. and Krzysik, et al. references are chemically compatible and, as such, the combination of compositions would not present any technical difficulties. Applicants' respectfully disagree. As noted above, the Klofta, et al. reference states that intentional addition of water to the anhydrous lotion they disclose would be detrimental to physical properties of the paper such as tensile and caliper. As such, Applicants' submit that there is no apparent reason to combine the components of the Krzysik, et al. reference, which are desirably incorporated into compositions having at least 13.5% by weight water, with the lotion compositions of Klofta, et al., which desirably comprise less

¹³ U.S. 6,440,437 at column 3, lines 61-67.

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than 5% (by weight) water, as Klofta, et al. teach away from the intentional addition of water to the anhydrous lotion.

Claims 15-18 and 20-22 depend directly or indirectly from claim 1 and are thus patentable for the same reasons as set forth above for claim 1 as well as for the additional elements they require.

2. Rejection of the Claims under 35 U.S.C. §103(a)

Reconsideration is requested of the rejection of claims 1 and 23-24 under 35 U.S.C. 103(a) as being unpatentable over Klofta, et al. (U.S. Patent No. 6,238,682) in view of Krzysik, et al. (U.S. Patent No. 6,440,437), further in view of Bowser, et al. (U.S. Patent No. 5,342,976).

Claim 1 is discussed above.

Klofta, et al. and Krzysik, et al. are discussed above. Significantly, as discussed above, Klofta, et al. and Krzysik, et al. each fail to disclose an antioxidant selected from the group consisting of butylated hydroxyanisole (BHA), butylated hydroxytoluene (BHT), carotenoids, filtered wheat germ oil, gamma oryzanol, sodium sulfite, grape seed extract, green tea extract, rosmarinic acid, ubiquinone, lipoic acid, N-acetyl-cysteine, avocado, sage, proanthocyanidins, and mixtures thereof.

Recognizing that Klofta, et al. and Krzysik, et al. fail to disclose each and every element of Applicants' claimed invention, the Office cites Bowser, et al. for combination with the Klofta, et al. and the Krzysik, et al. references. Specifically, the Office states that it would have been obvious

to a person having ordinary skill in the art to add a ceramide, such as glucosylceramide, as disclosed in Bowser, to a tissue product as there would be a beneficial effect of enhancing skin barrier function. The Bowser, et al. reference, however, fails to overcome the above shortcomings of the Klofta, et al. and the Krzysik, et al. references.

Bowser, et al. disclose a composition suitable for topical application to human skin. The composition comprises an active ingredient that can control skin barrier functions; particularly, the active ingredient can moisturize and treat skin surfaces that have become excessively dry, fissured, eroded, or otherwise damaged. Specifically, the active ingredient is (a) a long chain ω -hydroxy fatty acid or a carboxy-substituted derivative, (b) an hydroxy- or epoxy-derivative of an essential fatty acid, or an ester formed between (a) and (b). The composition further comprises a vehicle to enable the active ingredient to be conveyed to the skin in an appropriate dilution. One suitable vehicle is water. In one embodiment, the compositions can be used in a liquid-impregnated fabric, such as a tissue wipe.

As noted above, in order for the Office to show a *prima facie* case of obviousness, M.P.E.P. §2143 requires that the Office must meet three criteria: (1) the prior art references must teach or suggest all of the claim limitations; (2) there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to combine and/or modify the references, and (3) there must be some reasonable expectation of

success. An obviousness determination is not the result of a rigid formula disassociated from the consideration of the facts of the case. The common sense of those skilled in the art can demonstrate why some modifications and/or combinations would have been obvious where others would not.¹⁴ The Office has clearly failed to meet its burden under numbers (1) and/or (2) above, as the cited references do not teach or suggest all of the claimed limitations and there is no apparent reason to combine and/or modify the references to arrive at each and every limitation of Applicants' claim 1. It simply would not have been obvious to one skilled in the art to arrive at Applicants' claimed combinations.

Initially, with the Klofta, et al. and the Krzysik, et al. references, the Bowser, et al. reference, fails to teach or suggest including an antioxidant in their lotion, wherein the antioxidant is selected from the group consisting of butylated hydroxyanisole (BHA), butylated hydroxytoluene (BHT), carotenoids, filtered wheat germ oil, gamma oryzanol, sodium sulfite, grape seed extract, green tea extract, rosmarinic acid, ubiquinone, lipoic acid, N-acetyl-cysteine, avocado, sage, proanthrocyanidins, and mixtures thereof. As such, the cited references, alone or in combination, fail to disclose each and every element as required for a *prima facie* case of obviousness.

Furthermore, even if the cited references did show each element of Applicants' claim 1 (which they do not as Applicants' have explained above), neither the references themselves nor the common sense of one ordinarily skilled in the art would have

¹⁴ U.S. 6,440,437 at column 3, lines 21-29.

provided a reason to combine the Klofta, et al. reference with the Krzysik, et al. reference and the Bowser, et al. reference to arrive at Applicant's composition of claim 1.

As noted above, in establishing obviousness, the Office must show references that teach all of the claimed limitations along with some reason, either in the references themselves or in knowledge generally available to one skilled in the art, to modify and/or combine the references and arrive at the claimed subject matter.

Applicants assert that there is nothing in the cited references or in the general knowledge of one ordinarily skilled in the art, to combine the Klofta, et al., Krzysik, et al., and Bowser, et al. references to arrive at Applicants' amended claim 1. Specifically, similar to the Krzysik, et al. reference discussed above, a close reading of the Bowser, et al. reference actually teaches away from the combination of the Klofta, et al., Krzysik, et al., and Bowser, et al. references.

Specifically, as noted above, it is desirable for the lotion compositions of Klofta, et al. to be anhydrous lotions, typically comprising less than about 5% (by weight) water, preferably about 1.0% (by weight) or less water, more preferably about 0.5% (by weight) or less water, and most preferably about 0.1% (by weight) or less water.¹⁵ Further, as noted above, Klofta, et al. explain that the intentional addition of water to the anhydrous lotion would be detrimental to physical properties of the paper such as tensile and caliper. As noted above, however, the Bowser, et al. composition can comprise from about

¹⁵ U.S. 6,238,682 at column 10, lines 51-57.

15% to 99.9999% by weight water and, preferably from 50% to 99.5% by weight water. As such, there is no apparent reason why one skilled in the art would combine the components of the Bowser, et al. reference, which are desirably incorporated into compositions having at least 15% by weight water and, more preferably at least 50% by weight water, with the anhydrous lotion compositions of Klofta, et al., which desirably comprise less than 5% (by weight) water. As such, there is no motivation or apparent reason to combine the cited references to arrive at each and every limitation of Applicants' claim 1. As such, claim 1 is patentable over the cited references.

The Examiner submits on pages 10 and 11, paragraph 6, that the compositions of the Klofta and Bowser references are chemically compatible. Applicants' respectfully disagree. As noted above, the Klofta, et al. reference states that intentional addition of water to the anhydrous lotion they disclose would be detrimental to physical properties of the paper such as tensile and caliper. As such, Applicants' submit that there is no motivation or apparent reason to combine the components of the Bowser, et al. reference, which are desirably incorporated into compositions having at least 15% by weight water and, more preferably at least 50% by weight water, with the lotion compositions of Klofta, et al., which desirably comprise less than 5% (by weight) water, as Klofta, et al. teach away from the intentional addition of water to the anhydrous lotion.

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Claims 23-24 depend directly or indirectly from claim 1 and are thus patentable for the same reasons as set forth above for claim 1 as well as for the additional elements they require.

3. Double Patenting Rejections

Claims 1-30 have been provisionally rejected under the judicially-created doctrine of obviousness-type double patenting as being unpatentable over claims 1-61 of copending Application No. 10/659,969.

Applicants note this rejection is in fact a provisional obviousness-type double patenting rejection since U.S. Patent Application No. 10/659,969 has not yet issued as a patent. Applicants will address the merits of these rejections, as appropriate, if the listed application issues as a patent before the application at hand.

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CONCLUSION

In light of the foregoing, applicants request withdrawal of the rejections of claims 1-30 and allowance of all pending claims. The Commissioner is hereby authorized to charge any government fees which may be required to Deposit Account No. 01-2384.

Respectfully Submitted,

/Christopher M. Goff/

Christopher M. Goff, Reg. No. 41,785
ARMSTRONG TEASDALE LLP
One Metropolitan Square, 26th Floor
St. Louis, Missouri 63102
314-621-5070

CMG/JMB/dhm
By EFS